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Jane Henney, M.D.
Comissioner
Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville,MD 20857

July 14, 1999.

Dear Dr Henney,

I am writing in support of the approval of medical claims for the four substances submitted by Dr Whitaker et al. , namely:saw palmetto,psyllium husk seeds,the group of folic acid, vit.B6and B12, as well as Vit. E.

I came a long way from my ingrained conservativism in supporting health claims for nutritional supplements,but scientific scrutiny,interest of the public, and a desire to be truthful and reasonable, compells me to support these claims.

After graduation I worked in neurophysiological research at the Australian National University,follwed by working as a pharmacologist at the National Biological Standards Laboratory in Canbaerra, Australia.We held the FDA in high esteem, and considered the FDA manual as most helpful in quality and quantity assesement.We, or at least I, were not aware of the process of approval for labeling and claims.

My view started to change when I started to look into the best ways of prevention and reversion (hence, "therapy") of degenerative disease for myself.After reading alternative medicine books and journals with references to original publications and after joining the American Academy of Anti-Aging Medicine, I came to the conclusion, that FDA policy and regulations,not allowing any reference to disease or even symptoms, is a disservice to the people and to the advance of medical science. After all, almost anything we consider undesirable for ourselves has a name of a disease, a syndrome or symptom, not infrequently familiar to lay persons.

Extreme conservatism or adherence to medical dogma led to the difficulties of Semmelweiss and unnecessary deaths from puerperal sepsis, and a long list of similar situations occured after Semmelweiss.The list includes such simple substances as Magnesium to reduce the risk of toxemia of pregnancy,folic acid and trimethylglycine to rduce homocysteine, Vit. E to reduce CVD, and the list will grow.

In my opinion the FDA should introduce a fair labeling and informational practice as soon as possible, otherwise the public and physicians will be confused.Presently many of the physicians are completely uninformed about supplements, yet the supplement labels direct people to " ask your doctor".It is also my opinion that health claims for supplements are just as valid as for drugs if supported by scientific and empirical evidence, and if good quality is assured.Just look at the advertising contest between aspirin and tylenol, the two effective and useful and dangerous drugs.

I like to note that concensus opinion in my mind is a social-political, not a scientific opinion, where the dissenter(s) may be almost as likely to be validated by future findings as the concenters.

I wish the FDA to be a true and reasonable advocate for independent science and for the benefit of the people and I hope your leadership will lead to such a reputation of the FDA.

Yours truly,

Joseph Kiraly

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CROSS FILE SHEET

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